Item 3.1.2

FORMULARY AND MANAGED ENTRY SUBGROUP

Minutes of the meeting held on
Nov 28th 2017
12:30 - 2:30 pm
Pharmacy Dept. CMFT

Present:

Name	Title	Organisation	Jan	Mar	May	July	Sept	Nov
Elizabeth Arkell (EA)	Medicines Management Lead	UHSM	✓	A	✓	✓	✓	✓
Liz Bailey (LB)	Medicines Optimisation Lead	Stockport CCG	A	✓	A	✓	✓	✓
Dr Pete Budden (PB)	GP Prescribing Lead	Salford CCG *(Chair)*	A	✓	✓	✓	✓	✓
Sarah Boulger (SB)	Senior Medicines Information Pharmacist	The Pennine Acute Hospitals NHS Trust	A	A	✓	✓	✓	✓
Dr Paul Chadwick (PC)	Consultant Microbiologist and Chair of Meds Management Committee	SRFT	✓	✓	A	✓	✓	A
Aoidin Cooke (AC) (or Lorna Hand or Vanessa Reid)	Medicines Management and Medicines Information Pharmacist	CMFT	✓	LH ✓	✓	✓	VR ✓	✓ LH
Claire Foster (CF)	Senior Medicines Optimisation Advisor	SM CCG	✓	A	✓	✓	✓	✓
Dr Anne Harrison (AH)	Gp Prescribing Lead	Trafford CCG	A	A	✓	A	A	A
Leigh Lord (LL)	Locality Lead Pharmacist	Trafford CCG	✓	A	✓	A	✓	A
Keith Pearson (KP)	Head of Medicines Management	Heywood Middleton and Rochdale CCG	✓	✓	A	✓	✓	A
Prof Peter Selby (PS)	Consultant Physician	CMFT	✓	✓	✓	A	A	✓
Suzanne Schneider (SS)	MI Pharmacist	Bolton FT.	A	A	✓	✓	✓	✓
Lindsay Harper (LH)	Director of Pharmacy	SRFT	✓	✓	A	A	✓	✓

Jonathan Peacock (JP)	Deputy Chief Pharmacist	WWL	✓	✓	A	✓	✓	✓
Zoe Trumper (ZT)	Medicines Management	Pharmacist Wigan Borough CCG	✓	A	✓	✓	✓	A
Andrew Martin (AM)	Strategic Medicines Optimisation Pharmacist	GM Shared Service.	✓	✓	✓	✓	✓	✓
Bhavana Reddy (BR)	Head of Prescribing Support	RDTC *(Professional Secretary)*	✓	A	✓	✓	✓	A
Monica Mason (MM)	Principal Pharmacist Medicines Management	RDTC *(Professional Secretary)*	✓	✓	A	A	✓	✓

1. General Business

1.1 Apologies

Apologies had been received in advance as noted above.

Guest neurologist in attendance: Dr Paul Cooper (SRFT)

1.2 Declarations of Interest:

No declarations of interest were received in advance or made at the meeting.

1.3 Draft minutes (Sept 2017)

The minutes were agreed as accurate record following a minor amendment on the attendee list

1.4 Matters Arising

- Vitamin D Grey listing not approved by GMMMG – BR has contacted PS following discussions at GMMMG and is awaiting his response. MM to check the progress of this item
- Xultophy application – MM confirmed that there was no confirmed date for the launch of the glargine lixisenatide product product, and that the work plan would be updated to try and schedule both products together if feasible.
- Skin chapter review – the skin chapter had been opened for GM wide consultation

2. New Drugs or formulary assessments

2.1 Liraglutide (Saxenda® for obesity) – re-review of NTS recommendation as product now licensed

The group considered the current "Liraglutide for the treatment of obesity" statement which had been issued by the previous IPNTS group in 2014 (reviewed in 2016), in light of the fact that this product was now licensed. The group noted that placebo corrected weight loss of at least 5% as recommended by the EMA as a valid end point was not achieved in the SCALE-Diabetes clinical trial. One clinical trial showed that participants regained approximately 2kg within 12 weeks of discontinuation, and the group continued to have concerns that the phase III trials were limited to 56 weeks and were not representative of this long-term condition. Additionally the group were concerned that trial populations did not represent the population intended i.e. trial participants were likely to be more motivated given that there was a requirement for them to lose 5% of their body weight during the run-in period, and that use of LOCF approach may have over-estimated weight loss with liraglutide and under

estimated he response to placebo. Saxenda remains considerably more costly than other pharmacological options for obesity treatment, and there remains a lack of direct comparative data with other agents, and on other clinical outcomes. Therefore the group agreed that their position remained the same and that this agent would continue to be "not recommended".

Action: MM to communicate this decision to GMMMG and to update the statement as necessary

2.2 Trimbow – formulary assessment following pathway inclusion

The group considered an RDTC formulary assessment tool RDTC for Trimbow. Trimbow (contains 87 micrograms of beclometasone dipropionate, 5 micrograms of formoterol fumarate dihydrate and 9 micrograms of glycopyrronium (as 11 micrograms glycopyrronium bromide) and is licensed for the Maintenance treatment in adult patients with moderate to severe chronic obstructive pulmonary disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid and a long-acting beta2-agonist. The group noted that there was currently no single inhaler offering triple therapy has been commercially available (although further triple therapy inhalers are expected onto the market shortly). Currently, patients with COPD receiving triple therapy must use at least two inhalers, typically a combined inhaled corticosteroid plus long-acting β_2-agonist in one inhaler and a long-acting muscarinic antagonist in another e.g. fluticasone/vilanterol plus umeclidinium, beclometasone / formoterol plus tiotropium. This agent (and Trelegy Ellipta when launched) had been approved for inclusion into the GMMMG COPD pathway at the triple therapy stage as an alternative new treatment to Seretide 250/25 plus tiotropium handihaler. The group noted that Seretide 250/25 MDI plus tiotropium handihaler posed an annual cost per patient of £721.69 + £406.47, and that Trimbow costs £539.93 per pt per year and that there are about 66,000 pts in GM with COPD (which is below predicted prevalence), probably about a quarter of which should be in GOLD Group D i.e. needing ICS which represented nearly 16,500 patients. Many of these patients are likely receiving ICS already, but it was estimated that 10,000 existing pts could be stepped down off ICS.

The group approved the inclusion of these two agents into the formulary in line with the GMMMG COPD pathway, but recommended that a "green" status with a guidance note be assigned, to ensure that only those patients identified as continuing to need triple therapy received these agents, and to ensure that switch programmes did not inadvertently switch current patients to these new agents without first assessing whether there was a clearly identified continued need for triple therapy.

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the formulary will be updated accordingly.

2.3 Oscillating positive expiratory pressure device – formulary assessment

The group considered positive expiratory devices and whether there was a need for these devices to be positioned within the GM formulary. The group agreed that it was necessary to assess which specialities and departments would be recommending these products, group members agreed to seek feedback from their organisations and to return this information to the next meeting.

Action: FMESG members to consult with their organisations as to the intention to request PEP devices.

2.4 Femoston and Femoston Conti formulary application

The group assessed both products for formulary inclusion using an RDTC formulary assessment tool. It was noted that these products had been removed from the formulary in 2013, but since this time preparations such as Premique had been discontinued and agreed that both products should be re-inserted into the formulary to offer a choice of different progestogen.

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the formulary will be updated accordingly.

2.5 Pitolisant for narcolepsy – review of evidence and specialist opinion

The group considered the evidence for Pitolisant for narcolepsy with or without cataplexy and assessed it against the agreed decision making criteria. A NICE evidence summary (ES8, March 2017) reviewed two small randomised controlled trials (RCTs) of pitolisant 5–40 mg per day in adults with narcolepsy with or without cataplexy. Compared with placebo, pitolisant improved excessive daytime sleepiness, improved time awake in a darkened room and reduced the weekly cataplexy rate. Pitolisant was also compared with modafinil in a non-inferiority analysis (an analysis designed to test if it was not worse than modafanil for improving excessive daytime sleepiness by a pre-specified amount). Non-inferiority to modafanil was not shown. ES8 reported that the long-term safety data for pitolisant in people with narcolepsy are limited. Narcolepsy is an orphan disease, and clinical studies included small numbers of people for a short duration of time. In the two RCTs reviewed in ES8, the most common adverse events in the pitolisant groups were headache, insomnia, abdominal discomfort, nausea, irritability and anxiety. No participants in the pitolisant groups had withdrawal syndrome during the withdrawal phase.

NICE ESM8 states that the cost of 30 days treatment with pitolisant at a dose of 4.5 mg to 36 mg once daily is £310.00 to £620.00 (MIMS, February 2017, excluding VAT). The cost of 30 days treatment with other medicines used for narcolepsy is £6.06 to £318.24 for stimulants such as modafinil, dexamfetamine or methylphenidate and £540.00 to £1,080.00 for sodium oxybate (Drug Tariff, February 2017, excluding VAT). Greater Manchester Specialists expect very low numbers of patients requiring this treatment (<10 patients across GM per year). Whilst pitolisant is more costly that modafanil, methylphenidate and dexamfetamine, it would only be recommended for use where these treatments fail, and is less costly than sodium oxybate, which should be reserved as a final option.

Due to the specialist nature of this condition the group invited Dr Paul Cooper (neurologist, SRFT) to present his intention of use of this agent in the GM population. The group recognised that narcolepsy is a rare, disabling long-term brain disorder, often beginning in adolescence and usually diagnosed between 20 and 40 years of age. Pitolisant is the first of a new class of medicines licensed to treat this condition and provides an additional option to this group of patients. When considering a place in therapy for this agent the group accepted that there was little or no evidence versus other drugs and that the likely place in therapy is third line, after trials of modafinil and methylphenidate or lisdexamfetamine have failed or not been tolerated.

Action: MM to draft a recommendation to return to the January meeting and then to Dr Cooper for comment, after which it will be sent to GMMMG for approval.

3. Formulary

3.1 Formulary Amendments

The group considered NICE guidance published in Sept and Oct 2017 and MHRA drug safety updates from Sept and Oct. It was agreed that the formulary would be updated to reflect TA474 to TA488 and other NICE guidance as appropriate. Links to MHRA guidance would be included in the formulary. It was noted that fluphenazine was being discontinued at the end of 2018.

Action: MM to update the formulary chapters as appropriate

Formulary section review

3.2 Drugs used in diabetes – proposed changes

Following the GM consultation of the proposed changes to chapter 6 of the formulary, the group addressed the following items:

1) Proposal to list empagliflozin as the preferred local choice SGLT2 inhibitor with dapagliflozin as second choice and canagliflozin as third choice

This proposal was due to the result of the EMPA-REG trial, the group considered the comments received during the consultation and that NICE are in the process of producing a TA titled “Empagliflozin for reducing the risk of cardiovascular events in type 2 diabetes”. The group agreed that all three SGLT2s will remain in the formulary but a note would be added as follows “in individuals with type 2 diabetes and established cardiovascular disease, SGLT2 inhibitors with proven cardiovascular benefit (currently empagliflozin and canagliflozin) should be considered”

2) Bi-phasic insulins

It was agreed that biphasic insulins would remain in the formulary.

3) Liraglutide as first choice GLP-1

The group had discussed the positioning of liraglutide as the first choice GLP-1 following publication of the LEADER trial. It was agreed that a note will be added to GLP-1s as follows “For individuals with type 2 diabetes and established cardiovascular disease, GLP-1 receptor agonist therapies with proven cardiovascular benefit (currently liraglutide) should be considered. It was also agreed that the 3mg version of liraglutide (Saxenda) and pen needles will be assessed for DNP inclusion in the near future.

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the formulary will be updated accordingly.

3.3 Chapter 11 review (approval pre-consultation)

The group considered changes proposed by the primary and secondary care leads for the chapter 11 review. The main proposal was that a number of antibacterial eye drops currently listed as red drugs be transferred to green specialist initiation, as they were often required for a longer treatment course which resulted in patient inconvenience. The group was concerned that the extended treatment courses proposed rendered the some of these agents off-licence, and hence strengthened the need for their status to remain red. The group considered this issue to be a supply issue rather than a RAG (red, amber, green) issue, that longer term use of these agents may render the use off-licence as SPC states a shorter time and the risk to the patient if they are not being followed up appropriately or are receiving a treatment length that is longer than intended. The group asked that the specialist representatives be contacted for further discussion around alternative supply arrangements and that comments would return to the January FMESG meeting. The chapter will not be opened for GM wide consultation until a draft is agreed by FMESG.

Action: MM to contact lead reviewers as described above.

3.4 Blood glucose testing review

GMSS communicated to the group that GM CCGs are satisfied that the current choices and that this guidance will not be reviewed at this time. A note explaining this will be placed on the front page of this document and on the website.

4 RAG list

4.1 RAG consultation responses from Sept consultation

Following GMMMG pre-approval and GM wide consultation the following changes had been made:

Modafanil for PD was assigned a RAG status of red “pending SCP approval”

Prazosin for PTSD was added to the DNP list

Stiripentol for Dravet’s Syndrome was assigned a red status, following concerns received following GM wide consultation regarding the proposed amber status in adults.

4.2 Sildenafil for digital ulcers – RAG assessment

The group noted that although this is an unlicensed indication, it is supported by NICE ESM42 and an NHSE commissioning policy. As this is an off-label use for secondary severe Raynaud's phenomena associated with scleroderma treatment must be initiated and monitored by a specialist experienced in the diagnosis of Raynaud's disease, therefore it was agreed that a red status was assigned.

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the formulary will be updated accordingly.

4.3 Azathioprine for neurological conditions - RAG assessment

The group assessed this agent for a RAG status, considering the draft SCP in conjunction. It was agreed that am amber status be assigned to this agent but that the SCP to be amended to detail specific neurological conditions, and a red status would be assigned pending the approved SCP.

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the RAG list will be updated accordingly. MM to communicate this decision to the PaGDSG

5 DNP and Grey Lists

5.1 And 5.2 Herbal medicines and homeopathic medicines

It was agreed that herbal medicines and homeopathic medicines would be added to the DNP list due to their poor evidence base

Action: MM to submit recommendation to GMMMG for pre-approval, and then open for GM wide consultation, after which the DNP will be updated accordingly

6 Horizon Scanning and Work-plan

6.1 and 6.2

The group considered the RDTC October and November monthly horizon scanning documents and updated the work plan accordingly.

6.3 Strategy

The group were updated on the progress of the revised GMMMG CSB membership commencing in February 2018, a GMMMG work plan was being devised based on the GM strategy paper and would be used to direct the GM priorities through the subgroups.

7 Additional items

Nothing raised

The next meeting will be held on 23rd January 2018 at 12.30pm, CMFT.